MAXXIM MEDICAL

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October 26, 1999

Dockets Management Branch (HFA-305)
Food and Drug Administration
5630 Fishers Lane, Rm. 1061
Rockville, MD 20852

Subject: Comments: [Docket No. 98N-0313]

Dear Agency Member:

I wish to provide comments on the Food and Drug Administration's draft guidance entitled Guidance for Medical Gloves: A Workshop Manual. These comments are provided on behalf of Maxxim Medical, Inc., Clearwater, FL, a major medical glove manufacturer of both surgical and examination gloves.

Please refer to the attachment for applicable comments. Two copies are provided as requested.

Sincerely,

Joyce T. Moody

Joyce T. Moody
Vice President,
Regulatory Affairs/Quality Assurance

JTM:rmr

98N-0313

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CASE MANAGEMENT DIVISION
477 COMMERCE BLVD. • OLDSMAR, FL 34677 • (800) 727-7951 • FAX: (813) 855-2083

Docket No. 98N-0313
Comments

Expiration Dating

FDA has historically rejected expiration dating based upon accelerated aging studies. Should the requirement for expiration dating on all medical gloves (sterile and non-sterile) be imposed, FDA must allow manufacturers to use data collected from accelerated aging studies to substantiate the claim. Failure to do so would force glove manufacturers to delay the introduction of new products to the market and possibly affect the level of care available to consumers. The final rule, when published, must include the agency's recommended accelerated aging stability protocol or allow manufacturers the option to utilize their own validated method(s).

Labeling for Medical Gloves

- The proposed caution statements are lengthy. FDA should be sensitive to the problems created by requirements for the translation of the caution statements into as many as fourteen different languages, all appearing on each device label and product packaging. Provisions must be made to allow alternate methods for conveyance of information other than the principle display panel, which will achieve the ultimate goal to alert the user concerning NRL, powder and protein content of the medical gloves.

- There is no threshold amount of extractable protein that can be identified as the level that will not cause an allergic response in some individuals. The same is true for residual powder content levels. For this reason, the statement "FDA recommends that this product contain no more than 120 mg of powder and no more than 1200 μg extractable protein per glove" should be deleted from the proposed caution statements for powdered gloves. The similar statement in the proposed caution statements for powder-free gloves should also be deleted. FDA can accomplish the very same goal by publishing this information in the Medical Glove Guidance Manual. The publishing of recommended levels may erroneously imply that the user of the products so labeled is assured that the risk of an allergic reaction due to powder or protein content would be minimal. FDA should only require that manufacturers state the powder and protein content on primary packaging with no recommended limits stated.

- The requirement to state the protein content per glove instead of per gram of glove will cause concern by medical glove users because it will appear that the levels have suddenly increased. Glove weights per size have never been regulated by FDA; however, stating the extractable protein limit per glove automatically mandates the implementation of additional process controls for this variable throughout the production run. Re-education of the medical community, multiple packaging changes and additional process controls for this requirement are costly and add no value to the product and no additional benefit to the user.

Glove in Kits

The proposed rule requires convenience kit manufacturers to comply with the medical glove labeling requirements. This requirement places needless restrictions on the kit manufacturer in facilitating product substitutions where there is no stipulated user preference. To comply with the rule, the kit manufacturer would have to make labeling changes based upon the protein and powder content levels of each and every medical glove supplier for the kit. It is also feasible to have more than one type of glove within one kit, each with different levels of protein and/or powder. Additionally, kit manufacturers routinely purchase non-sterile latex examination gloves in bulk for placement in kits. The proposed guidance would eliminate this option and even place additional requirements on kit manufacturers to individually package latex exam gloves prior to placement in kits. This seems impractical since other latex-containing devices may be contained within the kits (catheters, tubing, etc.) that are not enclosed in the manner stipulated for latex gloves.

Proposed Effective Date
A two-year effective date should be allowed in order for industry to make necessary changes to processes, technology and labeling. The new requirements should not apply to the sale and distribution of products that were manufactured prior to the effective date of the guidance. Manufacturers must be given time to exhaust inventory of such stock without extreme negative impact on the company's ability to handle the cost of changes brought about by the new guidance requirements.

Reclassification of Medical Gloves
The rationale for reclassification of medical gloves into Class II is sound. We believe this to be a prudent action given the intended use of medical gloves in infection and contamination control.

Restrictions on Powder Glove Sales/Distribution/Use
The decision to ban the sale and use of powdered glove products does not appear to be warranted, based upon current facts and statistics.

- Although some reports suggest that powder may aid in the exposure of glove users to NRL proteins, similar concerns have not been established for powdered gloves made of synthetic materials. Sufficient studies must be conducted to compare and correlate user or patient reactions attributed to powdered synthetic gloves vs. powder free gloves of the same material.

- Sufficient time should be allowed to assess the impact of the proposed powder content limits on glove safety and efficacy. Perhaps the requirements to lower powder content on medical gloves will produce the desired level of patient/user safety without necessitating a complete ban on powdered products.

- Powder-free technology for medical gloves is fairly new compared to that of powdered glove processes. While manufacturers conduct all the required, and often additional, biocompatibility studies to ensure user safety, the technology and various powder-free coatings and formulations cannot purport to a long history of documented user safety. Given current knowledge of both the low incidence of powder-related user problems, and the short user history for powder-free technology, FDA's actions of issuing limits, for lower powder content on powdered gloves seems the most appropriate action to take at this time, to reduce adverse health effects from allergic reactions and foreign body reactions.

Limits: Recommended or Required?
FDA should state powder content and protein content limits as "required", rather then "recommended". The required limits should be stated in the Medical Glove guidance, not on the product labeling. This action would eliminate the proposed requirement to state the specific protein and powder contents on the primary labeling and reduce some of the costs associated with implementation of the guidance.

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